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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,723	10/29/2003	Jeffrey Allen	PA1425	4035
28390	7590	08/08/2006	EXAMINER	
MEDTRONIC VASCULAR, INC.			HOUSTON, ELIZABETH	
IP LEGAL DEPARTMENT			ART UNIT	
3576 UNOCAL PLACE			PAPER NUMBER	
SANTA ROSA, CA 95403			3731	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/694,723

Applicant(s)

ALLEN ET AL.

Examiner

Elizabeth Houston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>051806,020504</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: On page 7, the brief description for Figure 7 is missing.

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. For example page 21, Para 0061 line 1 has a typo --- "may connected".

Appropriate correction is required.

3. The disclosure is objected to because of the following: The description of Figure 2 at Para [0046] is confusing to follow because applicant is describing how two different elements fit together but is using the same number to refer to the same part of two different elements. A suggestion to overcome the objection would be to label one element 200 and the other 200' or to use 200a and 200b. The individual parts of each element should be re-labeled accordingly.

Appropriate correction is required.

4. The disclosure is objected to because of the following: It is unclear how *the second valley turn can be a longer valley than the first valley turn* as stated on page 10-11, Para [0034]. The specification states that second valley turn is *longer* than the first because it extends longitudinally *farther* than the first valley turn as a result of the mid-sized segment being longer than the short segment. However, examiner is confused how the valley turn extending farther has anything to do with its length. It appears that

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the valley turns have the same length and that the length of the segments is the variable factor affecting how far the valley turn extends longitudinally.

Appropriate correction is required.

5. The disclosure is objected to because of the following: In referring to Figure 4, Paragraph [0049] states, "The first valley turn 124 and second peak turn 136... have a larger turn radius 462 than first peak turn 112 and second valley turn 148." However in referring to Figure 5, Paragraph [0055] states, "The first peak turn 112 and second valley turn 148... have a larger turn radius 581 than smaller turn radius 583 of first valley turn 124 and second peak turn 136." It is clear that these two embodiments are contradictory to each other and therefor the specification has not been written in a clear and concise manner so as to portray what applicant intends to be the invention.

Appropriate correction is required.

Drawings

6. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the *details of the second adjacent element* as described in the specification on page 14, Para [0047] and as shown in Figure 2. All the parts being discussed are labeled, per se, however they are labeled for only one element and the specification makes reference to two elements. To avoid unnecessary confusion, each part of each element should be labeled such that they are given different but corresponding labels such as 101a and 101b; or 101 and 101'; or 101 and 201. Any structural detail that is essential

for a proper understanding of the disclosed invention should be shown in the drawing.
MPEP § 608.02(d).

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters have been used to designate more than one part in Figures 3 and 4. For example "104" has been used to designate both long segment of element 100a and long segment of element 100b; "112" has been used to designate first peak turn of element 100 and first peak turn of element 200. As stated in the previous paragraph, to avoid confusion same parts of different elements should be labeled such that they are given different but corresponding labels such as 101a and 101b; or 101 and 101'; or 101 and 201.

The application should be reviewed for other occurrences of the same issue that may not have been explicitly pointed out to avoid further confusion during prosecution.

7. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 3 states, "all but the first and last elements have a first and second connection point with an adjacent element", which is interpreted to mean that the first and last elements have no connection points. Claim 3 is dependent from claim 1, which states "elements are connected directly to adjacent elements". The specification is not enabling for an invention where "said elements are connected directly to adjacent said elements" and "all but the first and last elements have a first and a second connection point with an adjacent element".

10. Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no disclosure in the written specification or the drawings that depicts or explains how the “long segment of a first element *abuts* the short segments of a second adjacent element”.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Firstly, “last element” has not been introduced or defined in the previous claims. Secondly, using a negative limitation “all but” to define a claim limitation is not clear and concise and makes the claim indefinite. Finally it is unclear how the first and last elements do not have a first and second connection point with an adjacent element when claim 1 (from which claim 3 depends) states that the “elements are connected directly to adjacent said elements”. For purposes of examination, examiner will interpret the limitation as such: the first connection point exists between one main element and an adjacent element on a first side while the second connection point exists between that one main element and a second adjacent element on a second side. If this is what is intended then it should be further clarified. If it is not what is intended than appropriate correction should be made.

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13. Claims 19-22 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the peaks and valleys are being defined relative to the segments. Are the peaks and valleys included in the length of the segments or are the peaks and valley considered different entities from the segments. It is further unclear how the "long segments" of a first element abuts the "short segments" of a second adjacent element".

Claim Rejections - 35 USC § 102

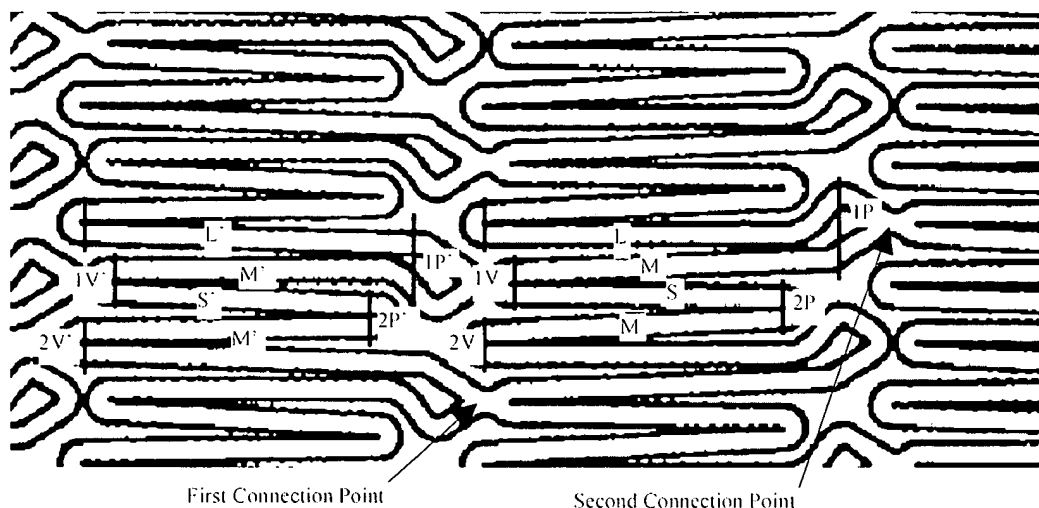
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-7, 9-13, 16-22 rejected under 35 U.S.C. 102(e) as being anticipated by Lowe et al. (US 2004/0093073).

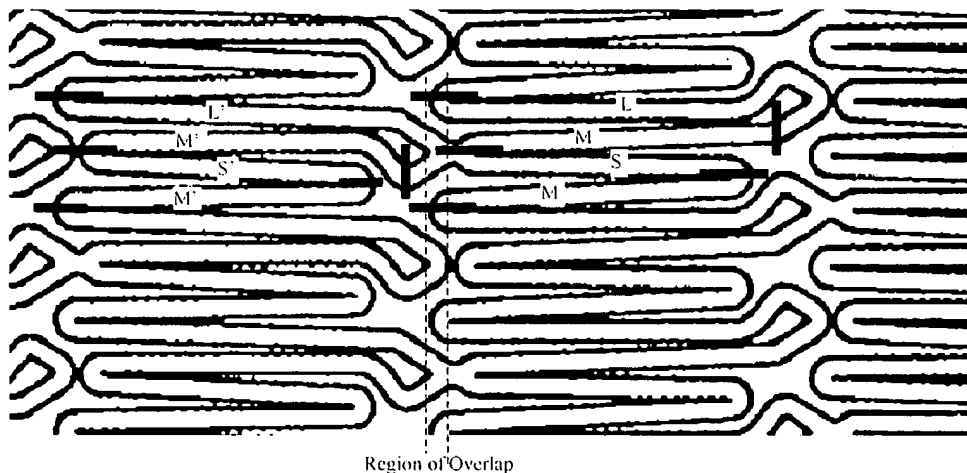
15. Lowe discloses a stent in Figures 23 and 24. The figure is copied and labeled below to depict the long segment (L), first peak (1P), midsize segment (M), first valley (1V), short segment (S), second peak (2P), and second valley (2V). It should be clear that the first peak turn of one element is connected to the first valley turn of an adjacent element. Each element (except the first and the last) has a first connection point connecting it to an adjacent element and a second connection point connecting it to a second adjacent element. The connection points form a double helix pattern. The

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elements are formed connected, welded or from toroidal rings (Para [0095]). The stent is balloon expandable (Para [31]).



For the purposes of claims 19-22 the following interpretation applies. The heavy black lines define where each segment begins and ends. The dotted lines define the area where the long segments overlap. The connection member spans between the long segment of the first element and the long segment of the second element because it extends between part of the long segment of one and part of the long segment of the other. Figures 11, 12 show embodiments where the connection is a sinusoidal.



Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 8, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe in view of Orth et al. (USPN 5,591,197).

18. Lowe discloses all the limitations of the instant invention substantially as claimed except for the first valley turn and the second peak turn has a larger turn radius than the first peak turn and the second valley turn.

19. Orth discloses a stent with different radii at different turns of the stent to accommodate differing expansion rates of the various members and to provide more uniform expansion.

20. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate turns with varying radii in order to enhance the function of the stent and provide the advantages as disclosed by Orth. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh




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SUPERVISORY PATENT EXAMINER

2/7/06